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Notice of Allowability	Application No.	Applicant(s)	
	09/419,461	KHALIL ET AL.	
	Examiner	Art Unit	
	Eric F. Winakur	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 24 October 2005.
2. ☒ The allowed claim(s) is/are 1,2,8-12,16-20,26-30,34-38,44-47 and 49-52.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Weinstein on 3 January 2006. Applicant agreed to amend the claims to more clearly set forth that the optical parameters are determined from the spatially resolved diffuse reflectance measurements and that all of the diffuse reflectance measurements are performed with distances of less than three millimeters.

The application has been amended as follows:

In the specification, the first sentence was amended as follows to update the status of the parent applications:

This invention is a continuation-in-part of U. S. Serial No. 09/080,470, filed May 18, 1998, now U.S. Patent No. 6,662,030, and is a continuation-in-part of U. S. Serial No. 09/302,207, filed April 29, 1999, now U.S. Patent No. 6,241,663.

In the claims:

Claim 1 was amended as follows:

1. A method of measuring at least one optical parameter of intact human tissue, wherein said at least one optical parameter is selected from the group consisting of absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, and light penetration depth, said method comprising the steps of:

(a) setting the temperature of said intact human tissue to a first temperature and allowing said intact human tissue to equilibrate at said first temperature before optical data are collected at said first temperature, said first temperature being within the range of from about 0 °C to about 45 °C;

(b) performing an optical measurement on said intact human tissue at said first temperature, wherein said optical measurement is a spatially resolved diffuse reflectance measurement;

(c) determining at least one optical parameter of said intact human tissue from said spatially resolved diffuse reflectance measurement at said first temperature, wherein said at least one optical parameter is selected from the group consisting of absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, and light penetration depth, said first temperature corresponding to a first depth in said intact human tissue;

(d) changing said first temperature of said intact human tissue to at least a second temperature and allowing said intact human tissue to equilibrate at at least said second temperature before optical data are collected at said at least said second temperature, said at least second temperature being within the range of from about 0 °C to about 45 °C;

(e) performing said an optical measurement on said intact human tissue at said at least second temperature, wherein said optical measurement is a spatially resolved diffuse reflectance measurement;

(f) determining said at least one optical parameter of said intact human tissue from said spatially resolved diffuse reflectance measurement at at least a second temperature, wherein said at least one optical parameter is selected from the group consisting of absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, and light penetration depth, said at least second temperature corresponding to a second depth in said intact human tissue; and

(g) determining said at least one parameter of said intact human tissue from the functional relationship of said at least one optical parameter on depth in said intact human tissue, wherein said optical measurements in step (b) and step (e) are carried out by transmitting light into a region of said intact human tissue at a light introduction site and collecting light re-emitted from said region of intact human tissue at a light collection site, wherein the distance between [the] any light introduction site and [the] any light collection site is less than three millimeters.

Claim 19 was amended as follows:

19. A method of measuring at least one optical parameter of intact human tissue having a plurality of layers, wherein said at least one optical parameter is selected from the group consisting of absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, and light penetration depth, said method comprising the steps of:

(a) setting the temperature of said intact human tissue to a first temperature and allowing said intact human tissue to equilibrate at said first temperature before optical

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data are collected at said first temperature, said first temperature being within the range of from about 0 °C to about 45 °C;

(b) performing an optical measurement on said intact human tissue at said first temperature, wherein said optical measurement is a spatially resolved diffuse reflectance measurement;

(c) determining at least one optical parameter of a first layer of said intact human tissue from said spatially resolved diffuse reflectance measurement, said first layer being located at a first depth of said intact human tissue, said first temperature corresponding to a first depth of said intact human tissue, wherein said at least one optical parameter is selected from the group consisting of absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, and light penetration depth;

(d) changing said first temperature of said intact human tissue to at least a second temperature and allowing said intact human tissue to equilibrate at said at least second temperature before optical data are collected at said at least second temperature, said at least second temperature being within the range of from about 0 °C to about 45 °C;

(e) performing said an optical measurement on said intact human tissue at said at least second temperature;

(f) determining said at least one optical parameter at at least a second layer of said intact human tissue from said spatially resolved diffuse reflectance measurement, said at least second layer being located at at least a second depth of said intact human

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tissue, said at least second temperature corresponding to said second depth of said intact human tissue, wherein said at least one optical parameter is selected from the group consisting of absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, and light-penetration depth; and

(g) determining said at least one parameter of said intact human tissue from the functional dependence of said at least one optical parameter on depth in said intact human tissue, wherein said optical measurements in step (b) and step (e) are carried out by transmitting light into a region of said intact human tissue at a light introduction site and collecting light re-emitted from said region of intact human tissue at a light collection site, wherein the distance between [the] any light introduction site and [the] any light collection site is less than three millimeters.

Claim 37 was amended as follows:

37. An apparatus for measuring at least one optical parameter of ' ' intact human tissue, wherein said at least one optical parameter is selected from the group consisting of absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, and light penetration depth, said apparatus comprising:

(a) a source of light for irradiating a region of said intact human tissue with light at [a] at least one light introduction site;

(b) a means for collecting light re-emitted from said region of said intact human tissue at [a] at least one light collection site, wherein the distance between [the] any light introduction site and [the] any light collection site is less than three millimeters;

(c) a means for changing the temperature of said intact human tissue to a temperature ranging from about 0 °C to about 45 °C so that radiation penetrates to a specified depth in said intact human tissue;

(d) a detector for measuring the intensity of the collected re-emitted light at a plurality of temperatures, wherein the measured intensities correspond to light re-emitted from different depths of said intact human tissue, wherein said intensity of said collected re-emitted light is used to determine spatially resolved diffuse reflectance of said intact human tissue; and

(e) a means for calculating at least one parameter of said intact human tissue from said spatially resolved diffuse reflectance and the dependence of at least one optical parameter on depth in said intact human tissue, wherein said at least one optical parameter is selected from the group consisting of absorption coefficient, scattering coefficient, mean free path, effective attenuation coefficient, and light penetration depth[, wherein said].


2. The following is an examiner's statement of reasons for allowance: It is noted that DE 196 34 152 (previously cited by Applicant) teaches optical measurements of tissue with spacing between an emitter and detector in a 3 mm range but does not teach or suggest spatially resolved measurements. Further, there is no suggestion in the prior art to apply this teaching in combination with any of the other references to provide a method or apparatus as set forth in the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571/272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur
Primary Examiner
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4 January 2006